

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
DALLAS DIVISION**

IN RE: DEPUY ORTHOPAEDICS, INC. PINNACLE  
HIP IMPLANT PRODUCTS LIABILITY LITIGATION

MDL No. 2244

Honorable Ed Kinkeade

*This Document Relates To:*

*All Cases*

**PEC'S MOTION FOR SANCTIONS AND TO COMPEL**

The Plaintiffs' Executive Committee, on behalf of the Plaintiffs' Steering Committee (PEC), files this Motion for Sanctions and to Compel regarding Defendants' failure to timely produce critically relevant documents.

Defendants at the eleventh hour, after eight years of litigation, recently produced a complaint received on its Ethics Hot-line<sup>1</sup> about Dr. Pam Plouhar that directly relates to testimony she has provided in bellwether trials in this MDL. The PEC requests, among other relief, that the Court sanction Defendants for the late production and compel them to produce unredacted copies of this complaint and all other complaints and related investigations and grant Plaintiffs the other relief specified herein.

As the Court knows, Dr. Plouhar served as the head of clinical research for DePuy for many years, and thereafter oversaw clinical research for all of Johnson & Johnson's medical devices. She notably oversaw the PIN Study, which has been shown in prior trials to have contained fraudulent data and results, and led to the infamous Kindsfater poster and Defendants' claims of a 99.9% success rate for the Pinnacle.

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<sup>1</sup> The "ethics hot-line" was mandated by the 2007 Deferred Prosecution Agreement, and allowed people to submit complaints or alerts regarding alleged unethical or improper conduct anonymously.

**I. Defendants failed to produce timely responsive documents.**

**A. Defendants were obligated to produce its ethics hot-line complaints.**

In 2013, the PEC served a deposition notice for Dr. Plouhar's deposition which requested production of documents relating to (a) "the Pinnacle Hip System" (Request no. 3), (b) "the safety of the Pinnacle Hip Systems (Request No. 4), and (c) "records relating to her employment status that refer to your job performance as it relates to any issues relating to the Pinnacle Hip System" (Request 7). (Exhibit 1 – Defendants' Response to Plouhar Deposition Notice). These requests reached any ethics complaints concerning her conduct as it relates to the MoM implants.

The PEC's ongoing review of documents and other investigation revealed the existence of an "ethics hotline" in early 2018, and Plaintiffs sent another request for production to Defendants specifically requesting "[a]ll Ethics Hotline complaints and subsequent investigation-related documents." Defendants responded that they would produce all responsive documents, subject to overbreadth and privilege objections. (Exhibit 2 – Defendants' Response to Plaintiffs' Interrogatories and Requests for Production of Documents, March 12, 2018).

**B. Late production of documents.**

Over the holidays, on December 21, 2018, Defendants produced some Ethics Hotline documents that redacted the identity of the complainant and the person receiving the complaint. On January 3, Plaintiffs requested non-redacted versions of the documents. Defendants produced the documents with modified redactions on January 7, but have yet to produce unredacted documents.

Defendants have not, however, produced their investigations of the complaints.

**C. Ethics hotline complaint against Dr. Plouhar.<sup>2</sup>**

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<sup>2</sup> As noted above, the PEC only recently received the ethics hotline information, and still have not received unredacted copies of those documents. The complaint detailed herein is merely one example of an egregious omission by Defendants. The PEC reserves the right to request other or

One of the late-produced documents is an Ethics Hotline Database Export dated March 31, 2013 and assigned complaint number 7640. (Exhibit 3 – DEPUY-R-113259867). It shows that a complaint was received from a former employee that he or she was unethically asked to participate in a ghost-writing scheme organized by Dr. Plouhar. The Court will recall that Dr. Plouhar has repeatedly refused to concede during the bellwether trials that DuPuy used ghostwriters to promote their MoM implants. The complainant contradicts Plouhar’s trial testimony; the complaint stated, “Pam Plouhar wanted me to ghost write articles so that she could get a bigger bonus. I refused and left J & J as a result.” The complainant stated that he or she was placed “on a no hire list” for “my refusal to help” Ms. Plouhar “by engaging in unethical/illegal ghostwriting, and for the embarrassment I caused her by electing to exit J&J instead of submitting to her unethical initiative toward me.” (*Id.*) In a letter submitted with the complaint the complainant stated, “the position they wanted me to fulfill was actually that of a ghost writer, and the government has been coming down hard on this. The government wants the public to know who writes papers for publication because the source of information may be related to bias and perceptions of bias.” (Ex. 4 – DEPUY-R-113259882). The complainant also alleged Dr. Plouhar “has taken many steps to conceal behavior on her part,” including that she “arranged a very strange termination of [name redacted] employment because Joni raised concerns of poor clinical trial management, for example.” (Exhibit 3, p. 12). The reporter who took the complaint described the complaint “case type” as an “allegation” of a “violation” but did not identify the implicated ethical, company, or legal standard. (*Id.* p. 2).

Dr. Plouhar was deposed shortly after this complaint was made, on August 13, 2013, and again on May 13, 2014. She has testified in all four bellwether trials, during

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additional sanctions, and additional discovery, once Defendants comply with their discovery obligations and make a full production of this important information.

which she was extensively cross-examined about the practice of “ghostwriting,” and denied that Defendants engaged in such activity – questioning about “ghostwriting” came up as early as the *Paoli* trial. (*See, e.g.*, *Paoli* Tr. Vol. 5 p. 87). The attached complaint calls into serious doubt the truthfulness of her prior testimony.

The PEC understands that Dr. Plouhar is no longer employed by Defendants, making it difficult to confront her with this information that directly bears on her former trial testimony.<sup>3</sup>

## **II. Legal Standard for imposition of sanctions.**

Fed. R. Civ. P. 26(g) authorizes the Court to impose sanctions for discovery abuse. Defendants certified to this Court on December 28, 2012 that after a production to be made “on or about December 31, 2012, those efforts [i.e. to identify, collect, and produce to Plaintiffs documents pertaining to the Pinnacle System and Ultamet Metal Insert and related matters] will be substantially complete.” (MDL 2244, Dkt. 241). Allegations of inappropriate conduct by Defendants’ Vice President for Clinical Affairs Worldwide – specifically as it relates to clinical study management and allegations of inappropriate “ghostwriting” – would obviously be relevant. Dr. Plouhar was not some obscure or relatively new employee; she was a Ph.D. scientist who was employed by Defendants from 1989 until her recent retirement, rising through the clinical research ranks. The failure to produce this important allegation, which directly impacts the testimony she has given in the prior four bellwether trials is outrageous.

In addition to the sanctions available under Rule 26(g) for discovery abuse, this Court has the inherent authority to impose sanctions on litigants or counsel who abuse the judicial process. *Chambers v. NASCO, Inc.*, 501 U.S. 32, 43-44 (1991); *Ramirez v. T&H*

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<sup>3</sup> It is not uncommon for former employees such as Dr. Plouhar to have a separation agreement that obligates her to continue to assist the company on certain matters, particularly matters relating to their former employment that are in litigation. Dr. Plouhar may have such an agreement with Defendants – the PEC does not have this information.

*Lemont, Inc.*, 845 F.3d 772, 776 (7<sup>th</sup> Cir. 2016), cert. denied, 16-1418, 2017 WL 2339748 (U.S. Oct. 2, 2017).<sup>4</sup> “As old as the judiciary itself, the inherent power enables courts to protect their institutional integrity and to guard against abuses of the judicial process with contempt citations, fines, awards of attorneys’ fees, and such other orders and sanctions as they find necessary, including even dismissals and default judgments.” *Shepherd*, 62 F.3d at 1472. This inherent power

reaches both conduct before the court and that beyond the court’s confines, for ‘[t]he underlying concern that gave rise to the contempt power was not . . . merely the disruption of court proceedings. Rather, it was disobedience to the orders of the Judiciary, regardless of whether such disobedience interfered with the conduct of trial.’

*Chambers*, 501 U.S. at 43 (citation omitted). Moreover, a court’s inherent power to punish a litigant’s misconduct is not limited to the conduct and sanctions identified in statutes or rules, but “extends to a full range of litigation abuses.” *Id.* at 42, 46, 49-50.

Such inherent powers “must be exercised with restraint and discretion.” *Id.* at 44; *Shepherd*, 62 F.3d at 1475. “A primary aspect of that discretion is the ability to fashion an appropriate sanction for conduct that abuses the judicial process.” *Chambers*, 501 U.S. at 44-45. The gravity of the sanction should correspond to the gravity of the misconduct. *Shepherd*, 62 F.3d at 1479. Although a “district court certainly can consider the extent of the prejudice to the opposing party when determining an appropriate sanction[,]” its “inherent power to sanction for violations of the judicial process is permissibly exercised not merely to remedy prejudice to a party, but also to reprimand the offender and ‘to deter future parties from trampling upon the integrity of the court.’” *Salmeron*, 579 F.3d

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<sup>4</sup> *Salmeron v. Enter. Recovery Sys., Inc.*, 579 F.3d 787, 793 (7th Cir. 2009); *Young v. Office of U.S. Senate Sergeant at Arms*, 217 F.R.D. 61, 65 (D.D.C. 2003); *Shepherd v. Am. Broad. Companies, Inc.*, 62 F.3d 1469, 1474-75 (D.C. Cir. 1995); *Compton v. Alpha Kappa Alpha Sorority Inc.*, 938 F. Supp. 2d 103, 105-06 (D.D.C. 2013); *Johnese v. Jani-King, Inc.*, CIV.A. 3:06CV0533-D, 2008 WL 631237, at \*1 (N.D. Tex. Mar. 3, 2008); *Daniel Rubin, P.C. v. Kerr*, CIV. A. 300CV1680G, 2001 WL 167965, at \*1 (N.D. Tex. Jan. 18, 2001).

at 797. *See also Ramsey v. Broy*, 08-CV-0290-MJR-DGW, 2010 WL 1251199, at \*6 (S.D. Ill. Mar. 24, 2010).

The Court has wide discretion to fashion an appropriate remedy when such abuses occur. Sanctions fall into two general categories. First, punitive sanctions are “fundamentally penal” and include “dismissals and default judgments, as well as contempt orders, awards of attorneys’ fees, and the imposition of fines...” *Shepherd*, 62 F.3d at 1478. *See also Compton*, 938 F. Supp. 2d at 106. Second, “issue-related” sanctions are “fundamentally remedial rather than punitive and do not preclude a trial on the merits...” *Shepherd*, 62 F.3d at 1478. *See also Compton*, 938 F. Supp. 2d at 106. These include adverse inferences or evidentiary determinations, striking defenses, or preclusion of evidence. *Shepherd*, 62 F.3d at 1478; *Young*, 217 F.R.D. at 70 (“Issue-related sanctions may include adverse evidentiary rulings and preclusion of specific claims, defenses or evidence, and taking certain facts as established.”); *Daniel Rubin*, 2001 WL 167965, at \*1.

Courts differ on the evidentiary standard that must be satisfied before a court can impose punitive sanctions. *Compare Shepherd*, 62 F.3d at 1472, 1478 (“[W]e hold that a district court may use its inherent power to enter a default judgment only if it finds, first, by clear and convincing evidence – a preponderance is not sufficient – that the abusive behavior occurred; and second, that a lesser sanction would not sufficiently punish and deter the abusive conduct while allowing a full and fair trial on the merits.”), *with Ramirez*, 845 F.3d at 775-81 (“In civil cases, the facts underlying a district court’s decision to dismiss the suit or enter a default judgment as a sanction under . . . the court’s inherent authority need only be established by a preponderance of the evidence.”). For **issue-related sanctions**, however, establishing Defendants’ misconduct by a preponderance of the evidence is sufficient. *Shepherd*, 62 F.3d at 1478 (“Because issue-related sanctions are fundamentally remedial rather than punitive and do not preclude a trial on the merits, we conclude that they do not require a heightened standard of proof. Rather, a district court may impose issue-related sanctions whenever a preponderance of the evidence

establishes that a party's misconduct has tainted the evidentiary resolution of the issue. The availability of issue-related sanctions sufficiently preserves a court's power to guard against abuses of the judicial process in those instances where the abuse is not proven clearly and convincingly."); *Daniel Rubin*, 2001 WL 167965, at \*1 ("Under its inherent power, a court may impose the sanctions of striking a defense or deeming a fact as established when 'a preponderance of the evidence establishes that a party's misconduct has tainted the evidentiary resolution of the issue.' ") (quoting *Shepherd*, 62 F.3d at 1478).

### **III. Requested Relief.**

Plaintiffs first request that Defendants be compelled to produce all relevant documents and information related to the requested documents. More specifically, Plaintiffs request the following:

- Defendants be required to produce, within five days, (1) all unredacted complaints received between 2001 and Dr. Plouhar's departure from Defendants' employ, or alternatively, any complaints or allegations of wrongdoing concerning or in any way related to Dr. Plouhar, ghostwriting, clinical studies, selection of physicians, withholding of information from physicians or the FDA, or any other matter related to safety or the MoM implants; (2) any documents reflecting investigations of the complaints, including any interviews, and (3) any severance agreement with Dr. Plouhar and identify her current address, and (4) Dr. Plouhar's entire, unredacted personnel file, including any performance evaluations and any exit interview for Dr. Plouhar, and the personnel file of any other of Defendants' employees accused of misconduct in any such complaint.
- Defendants be required to identify (1) Dr. Plouhar's last known address, employer, and phone number, and (2) the full name and the last known address, employer, and phone number of all individuals who made such complaints.
- Defendants be required to produce unredacted versions of all other complaints that relate to Defendants' orthopaedic implant business, including but not limited to complaints regarding alleged unethical or improper conduct by Defendants' sales representatives, as well as any documents reflecting investigations of such complaints.

As issue-related sanctions, the PEC requests (1) that they be granted leave to re-depose Dr. Plouhar and that she be compelled, after service by an appropriate subpoena, to testify at trial via satellite; (2) that they be permitted to depose any of the persons identified in the late-produced documents, and (3) any other form of issue sanction justified under the circumstances as additional facts develop.

With respect to punitive sanctions, the PEC reserves the right to seek an award of appropriate punitive sanctions once the facts surrounding Defendants' conduct are more fully known.

## **CONCLUSION**

Plaintiffs recognize that any relief to address this situation is entrusted entirely to the discretion of the Court. Any sanction should be tailored carefully to address and redress the relevant misconduct. Plaintiffs reserve, therefore, the right to request further sanctions upon the production of the information requested herein.

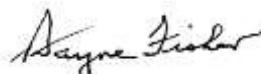
January 14, 2019.

Respectfully submitted:



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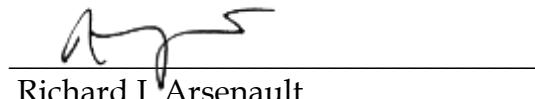


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**CERTIFICATE OF SERVICE**

I certify that the foregoing instrument was filed via the Court's CM/ECF system on January 14, 2019, and was also served on Defendants by electronic mail.



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Richard J. Arsenault